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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,057	02/05/2001	Colin Brown	9052-67	1282

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EXAMINER

WHITE, EVERETT NMN

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 05/21/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/700,057

Applicant(s)

BROWN, COLIN

Examiner

EVERETT WHITE

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 26-34 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 26-34 recites the limitation "said composition" and "the composition" in reference to Claim 23. There is insufficient antecedent basis for this limitation in the claim because Claim 23 does not refer to or recite a composition.

Claim 38 provides for the use of a composition according to Claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 38 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Objections

3. Claim 38 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 2, 4-10, 12, 13, 17, 18, 22 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies (US Patent No. 5,258,175).

Applicant claims a composition for preventing or reducing the incidence of adhesions in or associated with a body cavity comprising an aqueous formulation containing the polysaccharide dextrin.

The Davies patent discloses a dextrin derivative that is derived from a dextrin which is a glucose polymer mixture containing at least 15%, preferably at least 50%, by weight of glucose polymers of D.P. (degree of polymerization) greater than 12. Davies discloses the dextrin as having a weight average molecular weight of from 15,000 to 25,000 (see column 2, paragraphs 1 and 2), which fall within the weight average molecular weight range disclosed in instant Claims 8 and 9. Davies discloses the use of dextrin sulphate as the dextrin derivative (see column 2, line 11), which encompassed the subject matter of instant Claims 12 and 13. The Davies patent further discloses the present of electrolytes in a dextrin sulphate composition that may be selected as calcium or sodium (see the table in column 3, line 10), which embraces the subject matter of instant Claims 17 and 18. The examples set forth solutions of a dextrin sulphate composition that embraces the subject matter of instant Claim 2. The instant claims differ from the Davies patent by disclosing in the claims that the composition is for preventing or reducing the incidence of adhesions in or associated with a body cavity. Applicants are reminded that difference in intended use cannot render a claimed composition novel. Accordingly, it would be obvious to one of ordinary skill in this art at the time the invention was made having the Davies patent before him to obtain the claimed composition in view of the closely related structure of the dextrin derivative and similar components present in the composition.

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6. Claims 1, 3, 11, 14-16, 21, 22, 36, 37 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Viegas et al (US Patent No. 5,587,175).

Applicant claims a composition for preventing or reducing the incidence of adhesions in or associated with a body cavity comprising an aqueous formulation containing the polysaccharide dextrin.

Viegas et al discloses aqueous pharmaceutical vehicles comprising a film forming polymer and an ionic polysaccharide that can be gelled. The film forming polymer may be represented as polydextrin, sodium hyaluronate, chondroitin sulfate which embraces the presence of a polysaccharide dextrin, hyaluronate, and a glycosaminoglycan in a composition that are set forth in instant Claims 1, 11, 21 and 22. The Viegas et al patent discloses that the composition contain about 1% to about 50% by weight of the film forming polymer, which covers the amount of dextrin disclosed in instant Claims 14-16 when the film forming polymer of the Viegas et al patent is represented as polydextrin. The instant claims differ from the Viegas patent by disclosing in the claims that the composition is for preventing or reducing the incidence of adhesions in or associated with a body cavity. Applicants are reminded that difference in intended use cannot render a claimed composition novel. Accordingly, it would be obvious to one of ordinary skill in this art at the time the invention was made having the Viegas patent before him to obtain the claimed composition in view of the closely related structure of the dextrin derivative and similar components present in the composition.

7. Claims 1, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Apfeld et al (US Patent No. 5,230,933).

Applicant claims a composition for preventing or reducing the incidence of adhesions in or associated with a body cavity comprising an aqueous formulation containing the polysaccharide dextrin.

Apfeld et al discloses a composition comprising a cellulose ether, dextrin and lecithin (see abstract) whereby the lecithin is a mixture of naturally occurring phospholipids (see column 9, lines 55 and 56). See column 9, lines 64 and 65 of the

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Apfeld et al patent whereby the text indicates that lecithin is known to function as a lubricant. The instant claims differ from the Apfeld patent by disclosing in the claims that the composition is for preventing or reducing the incidence of adhesions in or associated with a body cavity. Applicants are reminded that difference in intended use cannot render a claimed composition novel. Accordingly, it would be obvious to one of ordinary skill in this art at the time the invention was made having the Apfeld patent before him to obtain the claimed composition in view of the closely related structure of the dextrin derivative and similar components present in the composition.

8. Claims 23-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Viegas et al (US Patent No. 5,587,175) in view of Milner (US Patent No. 4,886,789).

Applicants claim a method of preventing or reducing the incidence of adhesions in or associated with a body cavity, which comprises introducing into the body cavity an aqueous formulation containing the polysaccharide dextrin in an amount effective to prevent or reduce the incidence of such adhesions.

The Viegas et al discloses a process that involves injecting a composition that may be used as a medical device for the separation of organs, injured in surgical procedures or otherwise, in order to prevent the formation of undesirable adhesions as part of the healing process (see column 5, lines 2-6). Viegas et al discloses that the composition comprises a film forming polymer and an ionic polysaccharide that can be gelled whereby the film forming polymer may be represented as polydextrin, which embraces the polysaccharide dextrin set forth in the instantly claimed invention. The Viegas et al patent discloses that the composition contain about 1% to about 50% by weight of the film forming polymer, which covers the amount of dextrin disclosed in instant Claims 14-16 when the film forming polymer of the Viegas et al patent is represented as polydextrin. The instant claims differ from the Viegas patent by disclosing application of a composition to the peritoneal cavity. The Milner patent discloses a peritoneal dialysis composition containing an osmotic agent comprising a glucose polymer mixture (see abstract). See column 5, lines 60 and 61 of the Milner patent wherein it is indicated that the glucose polymer mixtures can be prepared by

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hydrolysis of starch. Since dextrin is prepared by hydrolysis of starch, the glucose polymer mixtures of the Milner patent encompassed dextrin. It would have been obvious to one of ordinary skill in the art at the time the invention was made to prevent adhesion of organs during the healing process as disclosed in the Viegas patent by applying the dextrin to the peritoneal cavity in view of the recognition in the art, as suggested in the Milner patent, that dextrin does not pass from the abdominal cavity through the peritoneal membrane and thus does not cause a rapid drop in the osmotic pressure.

Summary

9. All the pending claims are rejected.

Examiner's Telephone Number, Fax Number, and Other Information

10. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

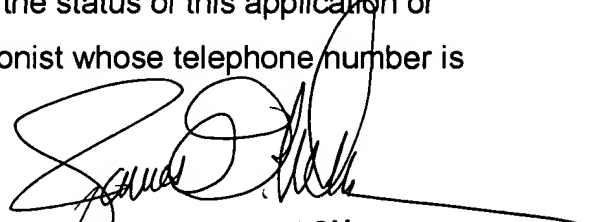
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter, can be reached on (703) 308-4532. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

E. White

E. White


JAMES O. WILSON
PRIMARY EXAMINER
GROUP 1600